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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SWARTZ, RODNEY P	
ART UNIT	**PAPER NUMBER**
1645	14

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/196,447	TRIPP ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7January2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43,45,50,52,53 and 55-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43,45,50,52,53,55-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicants' Response to Sequence Letter, received 8April2002, paper#12, is acknowledged. The CRF has been entered.

2. Applicants' Response to Office Action, received 7January2002, paper#9, is acknowledged. Claims 44, 46-49, 51, and 54 have been canceled without prejudice. Claims 43, 45, 50, 52, and 53 have been amended. New claims 55-59 have been added.

3. Claims 43, 45, 50, 52, 53, and 55-59 are pending and under consideration.

Rejections Moot/Withdrawn

4. The rejection of claims 44, 46-49, 51, and 54 under 35 U.S.C. '112, first paragraph, scope of enablement for antibody which selectively binds other proteins, is moot in light of the cancelation of the claims.

5. The rejection of claims 46 and 54 under 35 U.S.C. '112, first paragraph, scope of enablement for protecting a recipient animal from infection, is moot in light of the cancelation of the claims.

6. The rejection of claims 44, 46-48, 51, and 54 under 35 U.S.C. '112, first paragraph, scope of enablement for antibodies which bind to any and all other filariid p22U proteins, is moot in light of the cancelation of the claims.

7. The rejection of claims 44, 46-49, and 51 under 35 U.S.C. '102(b) as being anticipated by Tulloch et al (*Amer. J. Vet. Res.,* 31(3):437-448, 1970), is moot in light of the cancelation of the claims.

8. The rejection of claims 52 and 53 under 35 U.S.C. '112, first paragraph, scope of enablement for protecting a recipient animal from infection, is withdrawn in light of the claim amendments.

9. The rejection of claims 43, 45, 50, 52, and 53 under 35 U.S.C. '112, first paragraph, scope of enablement for antibodies which bind to any and all other filariid p22U proteins, is withdrawn in light of the claim amendments.

10. The rejection of claims 43, 45, 50, 52, and 53 under 35 U.S.C. '102(b) as being anticipated by Tulloch et al (*Amer. J. Vet. Res.,* 31(3):437-448, 1970), is withdrawn in light of the claim amendments and applicants' arguments.

Rejections Maintained

11. The rejection of claims 43, 45, 50, 52, and 53 under 35 U.S.C. '112, first paragraph, scope of enablement for antibody which selectively binds other proteins, is maintained.

Applicants argue that the specification, page 78, lines 2-9, indicate that immune serum selectively binds to recombinant *D. immitis* p22U protein, and does not bind to lysates of cells transformed with only the pTrcHisB plasmid (empty vector).

The examiner has considered applicants' argument, but does not find it persuasive in light of the amendment of the claims. The newly amended claims now recite "an isolated monoclonal antibody that selectively binds to a protein comprising amino acid sequence SEQ ID NO:4." Because of the open language "comprising", the protein of the claim not only encompasses proteins which consist of SEQ ID NO:4, but also proteins which in addition to the amino sequence SEQ ID NO:4, may have an unknown number of amino acids on either end of the known region, SEQ ID NO:4. Therefore, the scope of the newly amended claims also reads on antibodies which bind to these unknown regions. The specification does not provide sufficient support for these antibodies.

Rejecti ns Necessitated by Amendment

Claim Rejecti ns - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 43, 45, 50, 52, 53, and 56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polyclonal antibodies raised against larval stage *D. immitis* which bind to *D. immitis* p22U protein, does not reasonably provide enablement for monoclonal antibodies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention – monoclonal antibody that selectively binds to p22U protein.

The state of the prior art allows one of routine skill in the art to make a variety of monoclonal antibodies. However, there is a lack of predictability in the art concerning the production of a particular monoclonal antibody without proper direction or guidance.

The present application contains insufficient guidance/direction for producing a particular monoclonal antibody, i.e., one which selectively binds to a protein comprising amino acid sequence SEQ ID NO:4. In addition the specification contains no working examples of the claimed antibody.

Therefor, the quantity of experimentation necessary to produce the claimed antibody constitutes merely an invitation to experiment without a reasonable expectation of success.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 55, 57, 58, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tulloch et al (*Amer. J. Vet. Res.* 31(3):437-448).

The claims are drawn to an isolated antibody raised using an isolated *D. immitis* p22U protein, wherein said antibody is polyclonal, said protein is a recombinant protein, and wherein said protein comprises amino acid sequence SEQ ID NO:4.

The claimed antibody is a product by process. However, the process of producing the antibody, i.e., using isolated *D. immitis* p22U protein, does not appear to impart any structural or functional characteristics on the antibody to differentiate it from antibody produced using larval stage *D. immitis*.

Tulloch et al teach the production of antibody by immunizing dogs with larval stage *D. immitis*, the collecting whole sera from said dogs (section **materials and Meth ds**, pages 438-439; section *Serologic Test Results*, pages 442-443; Figures 5 and 6). The process of

obtaining serum entails isolation, i.e., isolating serum from whole blood. Therefore, while Tulloch et al do not utilize isolated *D. immitis* p22U protein, it would have been obvious at the time the invention was made to a person having ordinary skill in the art, that the resulting serum, in the absence of evidence to the contrary, would comprise isolated antibody which would be indistinguishable from an antibody obtained using isolated *D. immitis* p22U protein.

Conclusion

16. No claims are allowed.

17. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.

Rodney P Swartz

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

September 30, 2003